REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the following remarks. Applicants believe that the application is in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 12, 13, 15-24, 28-35, 37, 39-51 and 54-66 are pending in this application.

II. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 12, 15-24, 28-35, 37, 39, 40, 42-51 and 54-66 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Poet *et al.* and Meehan *et al.* in view of Nabel *et al.* Claims 13, 18-24, 37, 39, 41, 45-51, 65 and 66 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Poet *et al.* and Meehan *et al.*, in view of Mathiowitz *et al.* These rejections are traversed on several grounds and will be addressed collectively.

The current claims are directed to immunogenic preparations comprising at least one plasmid encoding and expressing PCV-2 ORF1 or PCV-2 ORF2, plus a cationic lipid and/or a carbomer, and methods for enhancing a host immune response using the preparations.

To the contrary and as has been pointed out previously, Poet relates to DNA vaccines against beak and feather disease virus (BFDV). While Poet does sequence and analyze the PCV-1 genome, there is **no** experimental data in Poet *et al.* relating to administration of a PCV-1 vaccine to animals or to elicitation of an immune response to PCV-1 in animals. The Examiner is reminded that a reference used in a prior art rejection must contain an enabling disclosure. *In re Hocksema*, 399 F.2d 269. Poet is not even enabling for a vaccine or an immunogenic preparation against PCV-1, let alone PCV-2.

As the Section 103 rejections have been maintained "for reasons of record", Applicants refer to the Office Action dated August 27, 2003, which sets forth the basis of the rejections. The Examiner's response to the argument that teachings of PCV-1 cannot be extrapolated to PCV-2 is found on pages 3 and 4 of the August 27, 2003 Office Action, where it states,

> the arguments are contradictory to the teaching of the original claims and disclosure, wherein PCV-1 and PCV-2 are included in the same Markush group. In the specification, both plasmids expressing PCV-1 and PCV-2 are considered as the preferred

> embodiment of the invention. Therefore, the original disclosure teaches that both PCV-1 and PCV-2 are effective immunogenic preparation [*sic* preparations]." (Citation omitted.)

This logic is entirely untenable. The Examiner is charged with examining the claims that are pending, not claims that were pending at some prior time in the prosecution history, and not subject matter that is disclosed in the specification but is not currently claimed. To apply a prior art reference to an embodiment of the invention that is not even claimed is ludicrous.

The second rebuttal to Applicants' arguments regarding Poet is based on the assertion that Poet "clearly teach[es] the correlation of PCV and pig wasting syndrome." The passage in Poet that the Examiner cites to support this conclusion reads, "A circovirus has also been implicated in 'postweaning multisystemic wasting syndrome' in swine herds in Canada." (Emphasis added.) It does not even say which circovirus.

While Applicants agree with the Examiner that Meehan *et al.* teaches "that PCV-2 rather than the classic PCV-1 is more closely associated with pig wasting syndrome" (bridging pages 3 and 4; emphasis added), it is an impermissible leap to equate a mere association with a disease to a positive identification of the pathogen causing the disease. The last sentence of Meehan reads, "The actiological role of PCV-2 in wasting syndromes in pigs is currently under investigation." This confirms that even the authors themselves could not assign a causative role of PMWS to PCV-2.

Conversely, Applicants unequivocally demonstrate in Example 10 of the instant application that infection of unvaccinated piglets with a PCV-2 viral suspension results in symptoms of PMWS. They further show that piglets are significantly protected by administration of a plasmid comprising at least one PCV-2 ORF. Meehan shows no such thing. At most, Meehan invites experimentation such as that described in the present application, but as the Examiner is aware, "obvious to try" is not the standard by which obviousness is measured under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988).

The Examiner argues that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Poet et al*, by simply substituting or including PCV-2 sequence when developing a vaccine for pig wasting syndrome as taught by *Meehan et al*, with a reasonable expectation of success." From where does this expectation of success come? There is no evidence of record that demonstrates expectation of

success, other than the Examiner's assertion that it is so. While Applicants agree that one would be motivated to develop a vaccine for PMWS, one cannot combine the teachings of Poet and Meehan and arrive at a viable way of doing so, particularly in view of the fact that all Poet and Meehan provide is an association between PMWS and PCV-2, without any experimental data showing a cause-and-effect relationship and without any attempt to produce a vaccine or immunogenic preparation containing any part of PCV-2.

Moreover, even if it the skilled artisan were aware, at the time of the invention, of the causal relationship between PCV-2 and PMWS, which, as discussed above, s/he could not have been based on the disclosures in Poet and/or Meehan, there is no basis for assuming that an effective vaccine could be produced. For example, we have known for twenty years that HIV causes AIDS, and we still have no efficacious vaccine to prevent HIV infection. The art of vaccine development is unpredictable, and the knowledge that a particular pathogen causes a set of symptoms or a disease does not automatically lead to the conclusion that development of an effective vaccine or immunogenic preparation is a matter of routine techniques.

In fact, this line of argumentation in the present Office Action and the August 27, 2003 Office Action directly contradicts the arguments of record in this application with regard to enablement. Pages 4 and 5 of the Office Action issued on April 17, 2001, enumerate the difficulties in developing DNA vaccines and the unpredictability of eliciting a protective response in vaccinated individuals. If the PTO is willing to ascribe enablement only to plasmids that have been exemplified and demonstrated to be effective, then it is invalid and illogical to now argue that the invention is obvious when none of the cited references have demonstrated any *in vivo* results at all.

The inclusion of Nabel and/or Mathiowitz in these rejections does nothing to remedy the deficiencies of Poet and Meehan, as neither teaches, suggests or even relates to an immunogenic preparation comprising any part of PCV-2.

Each and every element of the claims is not taught or enabled by the combination of the cited references, as is required for a proper art rejection. Further, as "obvious to try" would be the only standard that would lend the Section 103 rejections any viability, the rejection must fail as a matter of law. Therefore, applying the law to the instant facts, the rejections are fatally defective and should be removed.

In response to the statements on page 4 of the Office Action that the parent provisional application was filed in French and can therefore not be relied on for its priority date, the Examiner's attention is directed to the verified English translation that was filed in parent application no. 60/138,352 on September 8, 1999. Therefore, the requirements of 37 CFR §1.55 and MPEP §202.15 have been met.

Applicants request that the Examiner review MPEP §707.07(g), requiring that piecemeal examination be avoided as much as possible. It should be noted that no fewer than six Office Actions have been issued on this application, five of them **non-final**. The piecemeal examination that has predominated in this case has led to inefficiencies and unnecessary expenditures by both Applicants and the PTO, as well as extreme prejudice to Applicants in terms of shortened patent protection. Accordingly, if there are any further impediments to allowance of the pending claims that might be resolved telephonically, the Examiner is requested to contact the undersigned, in an attempt to avoid further delays in prosecution.

CONCLUSION

In view of the foregoing remarks, the application is in condition for allowance. Early and favorable reconsideration of the application, reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, are earnestly solicited.

Respectfully submitted,
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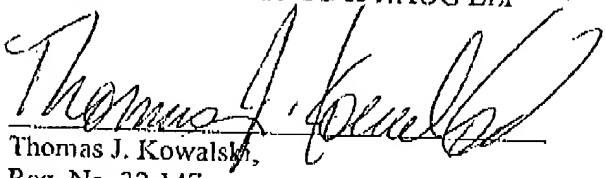
By: 

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